UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

6-October- 2000

MEMORANDUM

SUBJECT: **MALATHION Phase 4 Response**. HED's Summary and Response to Public Comments on the HED Preliminary Risk Assessment dated April 28,2000.
Chemical No. 057701
Case No. 0248
DP Barcode D267886.

FROM: Paula A. Deschamp, MS., Risk Assessor
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THRU: Alan P. Nielsen, Branch Senior Scientist
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TO: Patricia Moe, Chemical Review Manager
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This memorandum is HED's Phase 4 summary and response to comments submitted to the public docket (OPP-34223) during the public comment period regarding the preliminary risk assessment for malathion dated April 8, 2000. HED presents its response to comments in two parts.

Part I addresses comments received from individual citizens and various organizations as follows: Wisconsin Strategic Pesticide Information Project; American Nursery and Landscape Association; Oregon Strawberry, Blueberry, Raspberry and Blackberry Commissions; US Department of Agriculture's Animal and Plant Health Inspection Service; The Scotts Company; New Jersey Environmental Federation; Knouse Foods; Centers for Disease Control; National Coalition Against the Misuse of Pesticides (NCAMP); and Natural Resources Defense Council (NRDC). HED has summarized these comments by general topics to avoid repetition and to separately address comments that apply to regulatory or science policy issues that are not unique to malathion.

Part II addresses comments received from Jellinek, Schwartz & Connolly, Inc., on behalf of the registrant Cheminova A/S that are specific to malathion. For easy reference, HED has responded to Cheminova's extensive comments by using outline headings directly from their submission. Cheminova's comments appear in italics and are given verbatim or paraphrased for brevity. Only comments related to human health are addressed as follows: II. Carcinogenicity Classification for Malathion; III. Toxicology; IV. Supported Use Patterns for Malathion; V. Dietary Exposure Risk Assessments; VI. Response to EFED's Selection of Drinking Water Concentrations (as they pertain to human health risk); and VII. Occupational and Residential Exposure Risk Assessments.

This response memorandum was prepared with input from the following Malathion Team members: Jack Arthur, Environmental Scientist; Jerry Blondell, Ph.D., Health Statistician; Richard Griffin, Biologist; William O. Smith, Ph.D., Chemist; and Brian Dementi, Ph.D., Toxicologist.

RDI: BRSrSci:ANielsen

PART I - HED's Response to Other Public Comments

Part I: HED's Response to Other Public Comments		
Commentor(s)	**Comment(s)**	**HED's Response**
Comments Related to the Application of the 10x Factor		
Wisconsin Strategic Pesticide Information Project New Jersey Environmental Federation NRDC NCAMP	These commenters felt that EPA has failed to demonstrate the existence of reliable data for malathion to justify departure from the use of the FQPA 10x safety factor.	The Agency's policy for applying the FQPA safety factor is being addressed in conjunction with nine science policy issues which apply to all organophosphate active ingredients. OPP has developed criteria for retaining the default FQPA 10x safety factor or applying a different margin of safety supported by reliable data. In the case of malathion, the hazard assessment indicates overall high confidence that infants and children will be protected and finds no evidence of any special sensitivity to the young or other special intraspecies differences. Further, in assessing residential exposure potential, the Agency has chosen input parameters that have a bias toward protecting sensitive subpopulations.
General Comments Requesting Cancellation of Malathion Uses		
Private citizens New Jersey Environmental Federation NCAMP	These commenters urged the EPA to remove malathion from the home and garden market and/or restrict the use of malathion in a way that children are not exposed through drift from applications for agricultural or mosquito applications. One specifically voiced concern about sensitivities of children and the elderly and cited a report from Physicians for Social Responsibility entitled "In Harms Way, Toxic Threats to Child Development".	The Agency is very concerned about protecting the health of vulnerable populations and has criteria in place for assessing potential pre- and postnatal effects of chemical substances. These criteria are described in a draft Standard Operating Procedure (SOP) which was made available for public comment July 8, 1999. The Agency also routinely accounts for differences in sensitivity and variability between humans of different sexes and age groups in its risk assessments. Risks to children have been assessed for drift from the cotton treatment for boll weevil and for public health mosquito control, resulting in Margins of Exposure that are well above the target, and therefore not triggering the Agency's concern. Further, label language regarding standard methods for reducing risk from airborne pesticide drift will continue to be incorporated. The continued registration of malathion-containing products for the home garden market will be considered during risk mitigation.

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Testimonial Comments and Citations of Toxicological Research		
Private Citizen e:mail forward by Citizens Action Committee for Change (CACC)	Open literature citations related to human polymorphisms in organophosphate detoxification mechanisms were provided in support of a putative relationship between urban use of malathion for mosquito control and effects on human populations.	No specific link could be made between any of the chemical materials discussed in the cited literature articles to the spraying of malathion. Neither malathion nor malaoxon were specifically mentioned in any of the materials provided. In general, the abstracts from these literature articles indicate that polymorphism in the PON1 gene might lead to differences in response to organophosphate exposure among individuals in the general population. The Agency routinely accounts for differences in human susceptibility to the challenge of a chemical substance by applying a 10-fold intraspecies safety factor.
Private Citizen e:mail forward by CACC	This commentor provided a lengthy discussion on animal experimentation and expressed the opinion that LD50 tests are highly unreliable and have little relevance for human toxicity.	EPA has and continues to require LD50 testing to support registration of pesticides. EPA uses these test results to place appropriate warning and precautionary signal words on pesticide product labels.
Private Citizen e:mail forward by CACC	This comment was in the form of an verbatim reprint from Rachel's Environmental & Health Weekly containing references to military working dogs who served in the Vietnam War and were exposed to malathion and other pesticides. A relationship was drawn between testicular cancer in military dogs and the increase in testicular cancer in white males in many industrialized countries.	No specific link could be made between any of the chemical materials discussed in the newsletter reprint to the use of malathion.
Mary P.Buchwald Private Citizen	This commentor urged EPA to restrict the use of malathion and provided open literature citations suggesting that mixtures of chemicals pay a role in the potentiation of endocrine, immune, and behavioral changes.	No specific link could be made between any of the chemical materials discussed in the cited literature articles to the use of malathion. Neither malathion nor malaoxon were specifically mentioned in any of the materials provided.

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Comments on Supported Use Sites and Use Rates		
American Nursery and Landscape (ANLA)	The ANLA noted that use of malathion to control millipedes/combat pyrethroid resistance in commercial landscape/nursery operations is critical to the industry and fears that dropping greenhouse uses will further confound these problems.	This information will be further considered during risk mitigation, if necessary. At this point, the Agency has accepted an agreement by the registrant to drop all greenhouse uses of malathion.
Oregon Berry Commission Knouse Foods	Two commenters noted the importance of maintaining use of malathion on berry crops and emphasized malathion's role in IPM programs utilized by commercial blueberry growers.	This information will be considered during risk mitigation, if necessary. HED notes that the use of malathion on blueberries was included the Agency's preliminary risk assessment. The calculated REI for vine/trellis crops, which include blueberries, is 3 to 4 days, depending on the activity. This should not interfere with the actual average 7-day PHI reported by the commentor for blueberry growers.
The Scotts Company	Additional information was provided on the residential use of Scott's malathion-containing product (EPA Reg. No. 239-739). Scotts Company noted that it does not market malathion as a fogger or shaker can dust. Scotts also indicated they do not have directions for lawn uses.	This information, with particular emphasis on the label directions for lawn use, will be considered during risk mitigation. The Agency's risk assessment includes foggers and dust shaker cans because they are among currently registered label uses, even if not registered by Scotts Company. Regarding lawn uses, a check of the current label for Ortho® Malathion 50 Insect Spray (EPA Reg. No. 239-739) found that, for home invading pests - outdoors only, the instructions include to "spray lawns and a 10 ft wide strip along side of house." Other labels also include lawn uses, and therefore, this use site must be included in the Agency assessment.
Wisconsin Strategic Pesticide Information Project	The Agency has chosen to use maximum field residue trial rates to perform the assessment. Maximum label rates are mostly higher than the rates used.	The comment is accurate. However, it must be noted that the use of the field residue trial rates is based on agreement that these rates will be supported by the registrant, and that ultimately label rates for all malathion products will be revised to reflect the use rates assessed in the malathion RED document.

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NRDC	The EPA risk assessment lists a number of malathion uses that are not supported for reregistration, and are not included in the risk assessment. Yet these uses currently are registered and should be assessed for their exposure potential.	The uses listed in the EPA malathion risk assessment as not being supported were agreed upon by the EPA and the major registrant of malathion. It is the intention of the Agency that these uses will not be reregistered and therefore, at the conclusion of the reregistration process, the listed use sites will no longer present an exposure potential. Because the purpose of the risk assessment is to present a basis for making decisions on the reregistration of malathion, there is no reason to provide exposure/risk information on use sites which will not be included in that decision-making process. This is particularly true when aggregate risk plays an important role in the risk management decisions that must be made. Adding exposures to the calculation of malathion risk which have been identified, *a priori*, by the Agency as not being supported, would present an inaccurate risk profile.
CDC	It was stressed that malathion is one of the most important and effective public health pesticides available for controlling adult mosquitos and reducing the epidemic transmission of human disease.	The continued use of malathion as a public health pesticide to control mosquitoes will be considered during the risk mitigation phase of the reregistration process for malathion.

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Comments from other Federal/State Agencies		
CDC	The assessment is inconsistent in its reference to the non-occupationally exposed individual; referring to this as "non-occupational" exposure in some places, and "residential" exposure in others. The document should consistently refer to these exposures as, "residential," and use the term "non-occupational" only when referring to an occupationally-exposed person's exposure away from the job.	The EPA agrees that both terms are used. In the assessment the term "non-occupational" refers to exposures to an individual that do not result from the individuals occupational contact with the pesticide (i.e., either from handling the pesticide or working in treated fields). Residential exposure is a special subset of non-occupational exposure that is sometimes used interchangeably, although it is usually used when referring specifically to exposures being assessed in the residential setting. Other "non-occupational" exposures would include contact with treated turf in parks or schools. When these latter scenarios are assessed, they should be specifically identified. Occupational exposure is assessed separately from all non-occupational exposures. Guidance for the aggregation of risks under the Food Quality Protection Act specifically requires that they not be combined.
USDA APHIS	For more than 15 years, APHIS has been monitoring workers in its programs that use malathion, and there has been no evidence of adverse effects. Further, APHIS believes that adverse reactions (incident reports) to malathion at application rates used for the Boll Weevil Eradication Program or the Medfly Control Program are extremely rare. Symptoms described by potentially exposed individuals could be caused by other than malathion exposure. APHIS makes every effort to provide advance notification to potentially exposed individuals so that exposure can be minimized or avoided.	The Agency has provided in its risk assessment, a summary of incidents reports from a number of different organizations. Findings from these reports indicate that, in general, life threatening cases of malathion exposure have resulted from accidents while handling the concentrated formulation or extreme misuse (e.g., suicides). Milder, transient effects reported by exposed individuals cannot rule out malathion as the cause, even if the individuals were reacting only to the strong smell of the pesticide. Such effects will be looked at in the larger context of the overall risk management decision regarding the reregistration of malathion. This will include an analyses of the occupational handler and postapplication worker risks, which according to the Agency's analyses can be controlled by common mitigation approaches.

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CDC	The commentor noted that ULV droplet size and wind speed are critical factors in determining efficacy of malathion. The assessment does not present an REI for ULV malathion and should include a statement regarding this issue.	Key input parameters used in the AgDRIFT model have been listed in the assessment. Included in the model were the droplet size spectrum and assumed wind speed. Restricted entry intervals for ULV agricultural (maximum application rate of 1.22 lb ai/acre) were not specifically determined. However, REI calculations are dependent on application rate, and the REIs determined for field/row crops could be considered a reasonable screen for determining ULV ag crop REIs.
Comments Related to the Proposed Cancer Classification		
California EPA, Office of Environmental Health Hazard Assessment USDA, APHIS	OEHHA felt that the Agency's cancer classification "suggestive" was largely appropriate and provided definitive comments on: 1) why they do not agree with the use of cholinesterase data to conclude dosing was excessive; 2) the usefulness of the 18 month mouse study relative to tumorigenic response; and 3) why they favor a quantitative risk estimate. APHIS expressed the opinion that there is not enough weight of evidence to justify a "suggestive" classification of carcinogenic potential for malathion.	A meeting of the FIFRA/FQPA Scientific Advisory Panel was held on 17- and 18-August-2000 to review a set of scientific issues being considered by the Agency pertaining to an assessment of the human carcinogenic potential of malathion. Among the issues presented to the Panel was the Agency's proposed classification of malathion as "suggestive". The Panel's report of their recommendations on this issue is expected to be available in October.

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Comments Regarding Toxicity of Malathion in Chemical Mixtures		
Jim Moss Private Citizen	Noting Gulf War "Syndrome" concerns, this commentor provided literature citations of his research on: 1) synergism between DEET and malathion in cockroaches; and 2) potentiation of pyridostigmine bromide (PB) by selected compounds.	The Office of Special Assistant for Gulf War Illnesses has recently consulted with EPA on Agency methodologies for conducting bystander exposure assessments. Although a considerable body of literature exists on the potential for synergistic toxic effects from exposure to combinations of pesticides or other compounds, there are no data to evaluate the ability of malathion to potentiate the toxicity of PB. The EPA's proposed approach for identifying and categorizing pesticide chemicals that have a common mechanism of toxicity for purposes of assessing the cumulative toxic effects of such pesticides was announced in the 30-June-2000 Federal Register. When EPA completes its single chemical assessment of the organophosphate pesticides, it will conduct a cumulative exposure and risk assessment which will include malathion.

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Comments Regarding Enantiomers, Impurities and Degradation Products		
Robert K. Simon Private Citizen e:mail forward by CACC	Open literature citations related to the carcinogenicity of malathion were provided in support of a concern for increased human toxicity caused by malathion impurities and breakdown products.	In assessing the genetic toxicity of malathion and malaoxon, the Agency has reviewed a considerable body of literature on the topic as related to the weight of evidence conclusions regarding the carcinogenic potential of malathion.. The literature citations provided by Private Citizen Simon were introduced into the deliberations of an external peer review by the FIFRA Scientific Advisory Panel on 17- and 18-August-2000. The Panel's report of their recommendations on this issue is expected to be available in October.
Sue Riedman Private Citizen	This commentor submitted verbatim excerpts from the web site http://www.chemtox.com on issues regarding the toxicity of malathion degradates and the stability of these compounds at elevated temperatures.	HED routinely evaluates data on the stability of technical active ingredients at elevated temperatures and the storage stability of end-use products over a test period of at least one year. Such data provided on malathion indicate that malathion is stable for a year in warehouse conditions (20-23°C) although a small amount of isomalathion accumulated. The data also indicate that malathion is stable for 2 weeks at 100°F in dark; storage at 130°F in dark for 2 weeks resulted in increase of isomalathion. Both the materials data safety sheet and the label for a malathion 96.5% active ingredient end-use product give specific precautions that the product is not stable when stored at temperatures exceeding 55°C (131°F). These precautions are consistent with the data available to HED.
NRDC	EPA did not provide a reference for acute oral toxicity of malaoxon.	The agency used acute toxicity data on malaoxon from: Dauterman, W.C. and A.R. Main. 1966. Relationship between Acute Toxicity and *in Vitro* Inhibition and Hydrolysis of a Series of Carbalkoxy Homologs of Malathion. Toxicology and Applied Pharmacology. 9, 408-418.

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NRDC	EPA has stated that is does not know the relative ratios of the specific enantiomers in the technical products of cadusafos, naled, fenamiphos, isofenphos and profenofos, and presumably malathion — since the Human Health Assessment does not report enantiomer ratios under physical/chemical properties.	The issue of enantiomer toxicity has been raised in comments on many other organophosphate compounds. As in previous responses, the Agency agrees with NRDC's comment that enantiomers of a given substance may vary in toxicity and, therewith, pose different risks to human health or the environment. The Agency believes that the toxicity of malathion, its degradates, impurities or any of their enantiomeric forms present in the technical products used in malathion toxicity tests would be expressed in the toxicity data used in the risk assessment for malathion.
Comments Regarding Farm Worker and Residential Exposures		
NRDC	Farm worker children are an identifiable high-risk group deserving of health protection. Exposures to Farm worker children should account for not only residential use, but agricultural drift and exposure from tracked-in pesticides and contact with Farm worker's clothing upon returning home from work.	The Agency is concerned about exposures that can occur to the general population (including farm worker children) as a result of the occupational uses of pesticides. In a September 1999 presentation on residential exposure issues to the FIFRA Science Advisory Panel, the Agency proposed a methodology for calculating residential exposures and risks that result from spray drift that will be implemented when the revisions to the SOPs are finalized. The EPA's AgDrift Spray Model was used in this assessment to account for exposure to bystanders (residential) potentially exposed to malathion from agricultural (cotton boll weevil treatment) and public health mosquito control. The Agency is also actively engaged in developing policies and/or exposure assessment methods related to other potential exposure pathways such as take-home exposures related to the occupational uses of pesticides. Once these policies are in place, they will be used to consider exposures to the general population that may occur as a result of the occupational uses of pesticides. It is important to note that the residential exposure/risk assessment for malathion uses medium to high-end data and assumptions in the calculation of inhalation spray drift exposure and subsequent dermal and toddler incidental ingestion from the resulting residues on turf.

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New Jersey Environmental Federation	The use of malathion by homeowners is an unknown, and yet represents the segment of use most likely to expose individuals in their home environment.	While exposure monitoring data are not available specifically for homeowner use of malathion, there are sufficient data regarding residues on turf, application rates for homeowner products, assumptions regarding postapplication residential exposure scenarios, appropriate PHED surrogate handler unit exposure values and approaches from the Draft SOPs for Residential Exposure Assessment to adequately characterize exposure and risk from homeowner uses. Taken as a whole, the data, assumptions, use rates and standard values were chosen or employed in such a way that the resulting risk estimates are believed to be medium to high end (i.e., are protective of the largest majority of homeowners).
Private Citizen e:mail forward by CACC NRDC	EPA's preliminary risk assessment did not address the potential for the general public to be exposed as a result of the emergency use of malathion in Medfly Cooperative Eradication Programs.	The preliminary risk assessment for malathion does not address use of malathion to control medfly because only currently registered products are subject to reregistration eligibility decisions. The Agency has conducted separate risk assessments for the emergency use of malathion in Medfly Cooperative Eradication Programs under emergency exemptions (Odiott, et al.: D250394, D294875, D251682). Such exemptions may be granted to a state or another federal agency to allow use (for a limited period of time) of a pesticide product that is not registered for that particular use. The exemption is requested and authorized because a pest problem is unanticipated and/or severe and there is no time or interest by a registrant to register the product for that use. Registrants cannot apply for emergency exemptions.
NRDC CDC	Why is the use of malathion as a dusting agent to kill body lice not included in the risk assessment? EPA's aggregate assessment should have included exposure resulting from pharmaceutical use of malathion for head lice control.	HED did not identify any dust formulation uses of malathion registered under FIFRA to treat body lice. There is a non-FIFRA pharmaceutical use of malathion as a pediculicide for the treatment of head lice. This product is a lotion. The FDA approves and enforces uses of pesticidal-containing pharmaceutical products under FFDCA and the Agency is developing a process to determine if these uses should be considered in EPA's risk assessments.

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Comments Regarding Aggregate Exposure		
NRDC	It was noted that unlike many other assessments for OPs, the malathion document addressed aggregate dietary and non-dietary exposures. However, EPA did not include home garden uses, nor was a precise contribution to the risk cup from residues in water clearly stated.	HED provided an estimate of total MOEs for residential bystander pathways (public health mosquito control and off-target agricultural spray drift from aerial boll weevil programs) because of the unique circumstances regarding these special uses. The continued registration of malathion-containing products for the home garden market will be considered during risk mitigation.

PART II - HED's Response to Cheminova A/S Comments

II. CARCINOGENICITY CLASSIFICATION FOR MALATHION

A. Comment on EPA's Classification of Malathion

***Comment**:* *Cheminova disagrees with EPA's conclusion that data for malathion provide "suggestive evidence of carcinogenicity but not sufficient to assess human carcinogenic potential" and strongly believes that malathion should be classified as "not likely to be carcinogenic to humans."*

Response: A meeting of the FIFRA/FQPA Scientific Advisory Panel was held on 17- and 18-August-2000 to review a set of scientific issues being considered by the Agency pertaining to an assessment of the human carcinogenic potential of malathion. Among the issues presented to the Panel was the Agency's proposed classification of malathion as "suggestive". Cheminova also participated in this public meeting and presented their views on the cancer classification of malathion to the Panel members. The Panel's report of their recommendations on this issue is expected to be available in October.

B. Comment on EPA's Cancer Assessment Document #2

***Comment*:** *The last line on page 6 of EPA's data evaluation record (DER) for the PWG review of liver slides (EPA's May 30, 2000, document entitled "Malathion: Evaluation of the Cheminova Report Titled: A Pathology Working Group Review of Liver Slides from the 24-Month Toxicity/Oncogenicity Study in the Rat; (MRID #43942901), " states that the "CARC considered…and determined that there was no indication of a tumorigenic response for liver tumors in the female Fischer 344 rat." Cheminova notes that this conclusion was not included in the text of EPA's April 25, 2000, Cancer Assessment Document #2 (Report of the April 12, 2000, meeting). The conclusion stated in the DER should also be included in the Executive Summary on page ix and on page 49 (in Section IX, Classification of Carcinogenic Potential) of the April 25, 2000, Cancer Assessment Document #2.*

Response: HED has issued a memorandum (HED DOC. No. 014248, dated 19-July-2000) that corrects and supercedes the May 30, 2000 document. The correct statement is: **The Committee concluded that although the incidence of liver tumors in female rats was observed only at an excessively toxic dose (12,000 ppm), it provided evidence of carcinogenicity** because: 1) the incidence was statistically significant by pair-wise comparison; 2) there was a statistical trend; 3) the incidence was outside the range of both the testing facility and NTP historical control data bases. (014145 U.S. EPA 2000. Cancer Assessment Document #2, Evaluation of The Carcinogenic Potential of Malathion, Report of the 12-April-2000 Meeting and its 29 attachments. April 28, 2000.)

III. TOXICOLOGY

A1. Response to Data Gaps: 90-Day Feeding Study in Dogs (OPPTS 870.3150)

***Comment**:* *EPA is requiring a 90-day feeding study in dogs because it determined the available one-year study to be unacceptable. EPA classified the one-year study as core-supplemental, mainly because a NOEL for cholinesterase inhibition was not identified. Cheminova believes that a 90-day feeding study in dogs is not needed because available data from a one-year dog toxicity study (using six animals/sex/group) and a 28-day dog toxicity study (using three animals/sex/group) provide adequate information on the toxicity of malathion in non-rodent species.*

Response: On 15-August-2000, HED Hazard Identification Assessment Review Committee (HIARC) met to address this comment. The HIARC re-affirmed it's previous conclusion that a 90-day study in the dog is required. This conclusion was based on the following reasons: (1) ChEI showed a shallow dose-response in the chronic dog study; the NOAEL in the dog could be lower than the dose (chosen from a rat study) used presently for risk assessment, (2) the conduct of the study should be by the dietary route of exposure which is more appropriate than the capsule used in the previous study, and (3) an up-to-date methodology should be used to measure ChEI.

A2. Response to Data Gaps: 90-day Inhalation Toxicity Study in Rats (OPPTS 870.3465)

Comment: *Cheminova is considering conducting a new study using a tiered approach to define a NOAEL for nasal histopathology for the short- and intermediate-term inhalation exposure risk assessments. The study will be designed to demonstrate reversibility of any effects. Please note that Cheminova believes that in a previously conducted 90-day inhalation toxicity study (Beattie 1993), a clear NOEL for cholinesterase inhibition was achieved at 0.1 mg/L **:** the lowest dose tested.*

Response: On 15-August-2000, HED Hazard Identification Assessment Review Committee (HIARC) met to address this comment. The HIARC concurred with the registrant that a NOAEL has been established in the 90-day inhalation study in rats at 0.1 mg/L based on lack of statistical significance and the degree of inhibition could be within background level due to high variability. As indicated in the previous HIARC report, a new 90-day inhalation study (nose only) is required. Although a NOAEL has been established in the 1994 study, ChEI I data are still required in the new study. The new study should follow the Guideline 870.3465 protocol with measurements of ChEI and nasal histopathology.

B. Errors

Comment: *EPA is inconsistent in assigning biological significance based on ChEI inhibition results. The endpoint for chronic dietary and long-term (dermal) risk assessments is stated as inhibition of plasma ChEI activity. In the rat chronic toxicity/carcinogenicity study, it appears that EPA is not considering RBC ChEI inhibition of 17 percent at 500 ppm (not statistically significant) to be biologically significant. However, in the 90-day inhalation study , RBC inhibition of 8.9 percent (males) and 10.6 percent (females), also not statistically significant, is considered biologically significant thus concluding that the NOEL for ChEI inhibition was not established in the study. Cheminova believes the 90-day inhalation study shows a clear NOEL of 0.1 mg/L for RBC ChEI inhibition and suggests that EPA should be consistent and consider RBC ChEI inhibition biologically significant only when it is greater than 20 percent and/or statistically significant. EPA's conclusions from the 1-year dog study are also not consistent with its conclusions on the 90-day inhalation study (see III.A.1 above).*

Response: On 15-August-2000, HED Hazard Identification Assessment Review Committee (HIARC) met to address this comment. As noted above, the HIARC concurred with the registrant that a NOAEL has been established in the 90-day inhalation study in rats at 0.1 mg/L based on lack of statistical significance. The HIARC uses the weight of evidence approach in selecting endpoints and establishing NOAELs/LOAELs for risk assessments by considering all available data. The dose-response, statistical significance, numerical changes, variability and other factors are considered together before a final decision is rendered.

IV. SUPPORTED USE PATTERNS FOR MALATHION

A. Government Programs

Comment: *It is not appropriate for EPA to extrapolate potential risks from exposures associated with government-sponsored programs to potential risks from typical agricultural uses of malathion. EPA should conduct separate risk assessments for these programs (e.g., boll weevil eradication program, MedFly eradication program, and public health use for adult mosquito control), and present them separately from the agricultural uses.*

Response: HED has not extrapolated risks from government-sponsored programs to potential risks from typical agricultural uses of malathion for occupational and residential exposures. HED has presented a separate risk assessment for the USDA's Boll Weevil Eradication program using inputs that are specific to the use practices employed in that program. The assessment of public health control of mosquitoes appears as a separate use site in the occupational/residential exposure and risk tables, and includes inputs specific to the use pattern of the ULV formulation of malathion for mosquito control. In the case of HED's assessment of dietary (food) exposure, the residue inputs appropriately reflect all registered uses of malathion on cotton.

The use of malathion bait formulation specifically to control medfly was assessed separately as a FIFRA Section 18 registration action, and was, therefore, not included as a part of this reregistration action.

B. Supported Food/Feed Uses and Use Patterns

Comment: *EPA has made a policy decision to use maximum application rates from the residue field trials in support of food tolerances for reassessment of all agricultural uses. Many of the use patterns in EPA's Residue Chemistry Chapter (Table A2) are not supported by residue data. Cheminova clarifies the use patterns that were tested in the residue field trials in its Tables 2 - 6. EPA should revise its risk assessment using the information in these tables.*

Response: HED does not agree that a revised risk assessment based on the use pattern information provided in their Tables 2-6 is warranted. For clarity, HED has provided detailed information on the use patterns reflected in the field trials that were considered as the basis for HED tolerance reassessments and dietary risk assessments (see attached memorandum D268041, W. Smith, 16-Aug-2000). The Occupational and Residential Exposure and Risk Assessment has been revised and where appropriate, specific changes in the use rates have been used to recalculate occupational exposure and risks in the revised assessment.

C. Labels

Comment: *Cheminova appreciates the Agency's acknowledgment that there are end-use labels that include use patterns not supported by residue data and that it plans to take action on these labels during reregistration. For clarification, Cheminova requests that HED and EFED note in their RED chapters any use rates included in the risk assessments that are not supported by residue data.*

Response: HED has specifically identified use patterns that are not supported by Cheminova in the text of the risk assessment. These use patterns were originally agreed upon by the Agency, Cheminova and the IR4. Cheminova subsequently stated that it does not support certain other uses (e.g., turf uses). Support for these other uses will be determined during the mitigation phase of the assessment process after consultation with all affected parties.

V. DIETARY EXPOSURE RISK ASSESSMENTS

A. General Comments Regarding EPA's Dietary Risk Assessments

Comment: *Cheminova requests that data from the Organophosphate Market Basket Survey (OPMBS) be used to further refine the dietary risk assessments for malathion. They also note that a commodity contribution analysis that identifies the major exposure/risk contributors would be helpful for determining areas of focus for refining the risk assessments.*

Response: When the Organophosphate Market Basket Survey data become available, the malathion dietary exposure and risk analysis will be evaluated with respect to the results of the survey. HED will provide a commodity contribution analysis for malathion in conjunction with a revised DEEM analysis of chronic dietary exposure.

B. Errors Identified in EPA's Dietary Risk Assessments and Related Documents

Comment 1: *EPA's May 10, 1999, memorandum entitled "Anticipated Residues for Acute and Chronic Dietary Risk from Uses Being Supported for Reregistration" On page 1, EPA states that its chronic anticipated residues are "highly refined." However, EPA's chronic anticipated residues were determined based on the use of reassessed tolerances and maximum percent crop treated data. Refinements can be made to these anticipated residue estimates, including the use of residue data from single serving foods (either actual or imputed) and average percent of crop treated data. Therefore, we do not believe it is appropriate to refer to the current estimates as "highly refined."*

Response: HED again states that the **chronic** dietary risk assessment is highly refined and that all data currently available were considered. Chronic risk estimates for malathion are based on Pesticide Data Program (PDP) data, FDA surveillance data, percent crop treated, field trial data, and processing data. Monitoring data, percent crop treated data, and adequate field trial data were not available to refine the exposure estimates of all commodities. While HED agrees that this lack of data would tend to overestimate risk to some degree, it is not considered significant since the risk estimates of all population subgroups are less than 2% of the malathion cPAD.

The acute dietary risk estimates, based on tolerance level residues and an assumption of 100 percent crop treatment for all commodities are not refined, as pointed out by Cheminova. Since acute dietary risk assessment for malathion is not based on cholinesterase inhibition, a decision was reached to not refine the initial (screening) acute risk estimates which are below the aPAD for the total U.S. population subgroup.

Comment 2: *Cheminova requests that EPA correct the error on page 6 of the document: EPA's April 27, 2000, memorandum entitled "Malathion: Revised Dietary Risk Assessment". The text"at a level equal to or less than 46 percent..." should be consistent with the summary table that reports exposure less than 38 percent.*

Response: HED concurs and will make the appropriate corrections.

VI. RESPONSE TO EFED'S SELECTION OF DRINKING WATER CONCENTRATIONS

Cheminova's Comments HED's Response

Comment: *Although HED concluded that EFED's drinking water concentrations were not a dietary concern, Cheminova is providing these comments because these overestimates of malathion drinking water concentrations are scientifically inappropriate, and these overestimates could become more of a concern when HED begins conducting cumulative risk assessments*.

For surface waters, EFED used the Tier I runoff model GENEEC to estimate an acute malathion concentration of 226.0 ppb (although HED appears to have used a value of 322 ppb in its aggregate risk assessment), and an acute malaoxon concentration of 96.0 ppb.

Response: EFED will address the specifics of their drinking water concentration estimates. HED notes that the 322 ppb value used in its acute aggregate risk assessment reflects the sum of malathion at 226 ppb and malaoxon at 96 ppb.

VII. OCCUPATIONAL AND RESIDENTIAL EXPOSURE RISK ASSESSMENTS

A. Occupational Application Exposure and Risk Assessment

1. Mathematical Errors

Comment 1: *In Table 6, on page 34, for the ULV mosquitoes flagging scenario, the daily dermal dose should be 0.54 mg/kg/day, the dermal MOE should be 93, and the ARI should be 0.82.*

***Response*:** EPA agrees, and corrections in the table have been made regarding the daily dermal dose and dermal MOE. Further, in its revised occupational/residential chapter, HED has used a different risk metric in which risk calculations for dermal and inhalation exposures are expressed as total MOEs rather than ARIs.

Comment 2: *In Table 6, on page 34, for the turf scenario, the daily dermal dose should be 0.48 mg/kg/day, the dermal MOE should be 110, and the ARI should be 1.0.*

***Response*:** EPA agrees. A recalculation of this scenario indicated that a math error had occurred. The daily dermal dose should be 0.44 mg/kg/day and the dermal MOE should be 115. These changes have been made in the

table. Further, in its revised occupational/residential chapter, HED has used a different risk metric in which risk calculations for dermal and inhalation exposures are expressed as total MOEs rather than ARIs.

Comment 3: *With the correct ARI of 1.0 for turf, the PPE-mitigated flagging scenario for turf should be removed from all lists of scenarios that are of potential concern.*

Response: An appropriate change in the list has been made for this scenario, based on the combined MOE approach. A recalculation of total MOEs indicated the need for only one PPE-mitigated flagging scenario: the turf application scenario.

Comment 4: *In Table 7, page 37, the dermal unit exposure for enclosed cab flagging scenario is based on the enclosed cab groundboom application. EPA should follow guidance in the PHED Surrogate Exposure Guide (1998), and use a 98% reduction factor to the open flagger unit exposure, just as it has done for the closed cab flagger inhalation unit exposure.*

***Response*:** EPA agrees. The 98% reduction factor has been applied to the enclosed cab flagger scenario, per PHED guidance.

2. Apparent Omissions

Comment 1: *Exposure calculations contain applicator exposures for groundboom spraying, aerial and airblast spraying of berries, but the risk assessment does not include the corresponding mixer/loader exposure estimates for these three scenarios.*

***Response*:** Mixer/loaders are assessed for malathion wettable powder (WP) use on berries (see scenarios 3a, 3b and 3c). The WP was determined to be the appropriate formulation to assess for use on berries.

3. Supported Crops and Uses

Comment 1: *EPA assessed occupational and residential exposures for application of malathion to lawns. However, Cheminova is not supporting applications of malathion to lawns. Because all other registrants are relying on Cheminova's data to support their registrations, Cheminova believes its decisions regarding the continued registration of malathion should be regarded as applicable to all other end-use registrations. Uses of malathion on turf will not be included on Cheminova's revised technical label. Therefore, Cheminova requests that all application scenarios concerning potential dermal exposures to treated turf be removed from the occupational application risk assessment.*

***Response*:** Because turf uses (e.g., Ortho® Malathion 50 Insect Spray, EPA Reg. No. 239-739, sprayed on lawns to control clover mites) are currently registered, their potential exposures and risks are included in the current assessment. If official removal of these uses for malathion is to occur, it will be done during the risk mitigation phase of the reregistration process.

4. Crop Groups and Application Rates

a. Agricultural Crop Groups and Application Rates

Comment 1: *The crop groups utilized by EPA in the revised occupational and residential risk assessment are difficult to understand and appear to contain errors. Some crop groups are overly broad and/or inconsistently defined. EPA should clearly define the set of crops that constitute each crop group. Most importantly, the maximum application rates assumed by EPA for each crop group do not correspond to the maximum application rates that were tested in residue studies and are being supported for reregistration. Cheminova recommends that the agricultural crops be organized according to the crop groups specified in 40 CFR, Part 180. Such a listing is provided by Cheminova in Table 10 of the submission.*

***Response*:** EPA agrees. The grouping of crops supported by residue field trial data have been revised in the use pattern

section of the document according to the groupings given in 40 CFR Part 180, along with application rates from field residue trials. However, assessment of the entire list of crop groupings, in combination with various formulations, application rates and methods of application raises practical problems regarding the length, complexity and presentation of the assessment. Therefore, EPA has changed the assessment to include a range of representative crop groupings and application rates that bracket the major potential risks from the use of malathion. Listed as Ag low, Ag medium and Ag high these groupings represent the Brassica vegetables (1.25 lb ai/acre); leafy vegetables and berries (2.0 lb ai/acre); and pineapples (5.0 lb ai/acre), respectively. Separate assessments were included for citrus, pome and stone fruits.

b. Application Rates for Ornamentals, Shade Trees, and Pine Trees

Comment 1: *Cheminova questions the derivation of the application rate used by EPA for malathion EC use on ornamentals and pine trees (2.6 lbs ai/acre).*

Cheminova points out that the maximum application rate on ornamentals, flowers and shade trees is 1.25 lbs ai/100 gal (for 8EC) and 2.5 lbs ai/100 gal (for 5EC), without any specifications for the number of gallons to be sprayed per acre. Cheminova suggests using 100 gallons per acre as an assumption.

Cheminova points out that the maximum application rate for EC forestry uses is 0.9375 lb ai/acre (1.0 lb ai/acre for ULV).

Cheminova requests that EPA separate the assessments for ornamentals and forestry uses.

***Response*:** After re-evaluation of currently registered labels, EPA has changed the application rate to 2.5 lb ai/acre. However, because open forest use is not supported and because ornamentals and pine tree seedlings can be treated similarly, the maximum rate of 2.5 lb ai/acre is used to bracket the potential risk from such uses, including pine tree forests.

c. Application Rates for Mosquito Control

Comment 1: *EPA assumed a maximum application rate for ULV mosquito control (mixer/loader and applicators) to be 0.5 lb ai/acre. For postapplication exposure assessment, EPA used 0.23 lb ai/acre. Cheminova supports the latter use rate, and requests that EPA revise the risk assessment, using the 0.23 lb ai/acre use rate for all scenarios, as the appropriate rate.*

***Response*:** EPA agrees. The 0.5 lb ai/acre rate is appropriate for non-ULV larval mosquito control, whereas, 0.23 lb ai/acre is the appropriate rate to represent all public health ULV mosquito control activities. This change has been made in the assessment.

d. Application Rate for Berries

Comment 1: *EPA assumed a maximum application rate of 4 lb ai/acre for berries. The application rate being supported for berries is 2 lb ai/acre for EC and WP formulations and 0.76 lb ai/acre for ULV formulations.*

***Response*:** The assessment has been changed to reflect the supported use rate of 2 lb ai/acre for the EC and WP. The maximum ULV rate for all ag crops (i.e., 1.22 lb ai/acre) has been used to bracket potential risks for all ULV ag applications.

5. Irrelevant Occupational Exposure Scenarios

Comment 1: *EPA scenario 11 (applying to turf with a handgun) should be removed because Cheminova is not supporting turf use of any kind. Cheminova believes its decision regarding malathion registered uses*

should be regarded as applicable to all other registrations because it has submitted all of the data to support malathion reregistration and all other registrants are relying on Cheminova's data, as well.

***Response*:** As previously noted, a decision regarding the support for turf use will be made during the mitigation phase of the reregistration process.

Comment 2: *EPA scenario 15 [14] (mixing/loading/applying with a paintbrush for mosquito control) should be eliminated from the assessment. Cheminova is unaware of any such use.*

***Response*:** One such use is Sunbugger #6 (EPA Reg No. 9754-6), which is applied by paint brush under eaves, along foundations and other areas frequented by pests such as crickets, spiders and ants.

Comment 3*:* *EPA scenario 16 (flaggers) for mosquito control should be eliminated because for large acreage involved, GPS or other technical guidance systems are used.*

***Response*:** A note has been made in the RED document that the use of human flaggers for public health mosquito control scenario is unlikely, due to the large number of acres covered per application. Current label language does not preclude the use of human flaggers.

6. Assumptions for Daily Treatment Rates

a. Low-pressure Handwand

Comment 1: *EPA assumed that five acres would be treated per day. Other EPA organophosphate assessments have used a 40-gallon per day assumption. Cheminova believes the consistent use of 40-gallons per day assumption should be used for this scenario.*

***Response*:** The HED Exposure Science Advisory Council Policy #009 (revised July 2000) lists the standard value for daily treatment using a low-pressure handwand as 40 gallons. The assessment will be changed to use this rate.

b. Backpack Sprayer

Comment 1: *EPA assumed that five acres would be treated per day. Other EPA organophosphate assessments have used a 40-gallon per day assumption. Cheminova believes the consistent use of 40-gallons per day assumption should be used for this scenario.*

***Response*:** The HED Exposure Science Advisory Council Policy #009 (revised July 2000) lists the standard value for daily treatment using a backpack sprayer as 40 gallons. The assessment will be changed to use this rate.

c. Handgun Sprayer

Comment 1: *EPA assumed that five acres would be treated per day for turf. Cheminova is not supporting any turf use and requests that all such uses be eliminated from the EPA assessment.*

***Response*:** As previously noted, a decision regarding the support for turf use will be made during the mitigation phase of the reregistration process.

7. PPE Assumptions

Comment 1: *Currently, Cheminova labels require handlers to wear long-sleeved shirts, long pants, socks, shoes and chemical- or water-resistant gloves (except for flaggers, who need not wear gloves). Cheminova is conducting meetings with stakeholders to determine a consistent set of PPE requirements for malathion products and will share the outcome with EPA.*

***Response*:** The EPA risk assessment in the RED document presents PPE requirements for achieving the target MOE. The assessment is based on short-, intermediate and long-term toxicity endpoints. This assessment may result in mitigation requirements that are more or less stringent than those imposed under the Worker Protection Standard (WPS), which are based on acute toxicity of the end-use products. Final label requirements for PPE will be determined during the mitigation phase of the reregistration process, taking into account the requirements of the Worker Protection Standard and the indications for risk mitigation resulting from the EPA risk assessment. Addition of PPE requirements that are unnecessary to reach target MOEs or comply with the WPS, are not advised because they may result in heat stress or other health problems with no counter-balancing health benefit.

8. Unit Exposures

a. Open Pour Mixing/Loading of Liquids

Comment 1: *EPA used unit exposure values for open pour mixing/loading liquids from the PHED Surrogate Exposure Guide (1998). Data upon which the surrogate values were based were generated under conditions that bear no resemblance to occupational uses of malathion. A vast majority of malathion uses would have workers handling 26 to 1,750 lb ai/day in equipment having spray tanks of at least 100 to several hundred gallon capacity. The data utilized by EPA consists of replicates in which small tank sizes and relatively small amounts of active ingredient were used. The surrogate guide should not be used if data are not appropriate for the situation of interest. Cheminova evaluated the data in PHED, selected representative data, and estimated unit exposures. Specifically, two of the criteria used to select PHED data sets were: spray tank size of 100 gallons or more; and, active ingredient handled as 20 lb or more. The resulting subset contained 109 records. Utilizing A or B data from this subset, Cheminova determined inhalation exposure unit exposure to be 1.2 ug/lb ai. The dermal unit exposure (excluding hands) was determined to be 10.5 ug/lb ai. Hand unit exposure was determined to be 0.13 ug/lb ai. Cheminova requests EPA to use these revised unit exposure estimates in its risk assessment for open pour mixing/loading liquids, except for grape-dipping and non-thermal foggers, where workers handle much less product per day. In the latter two scenarios, Cheminova recommends using values from the PHED Surrogate Exposure Guide.*

***Response*:** EPA agrees with the approach suggested, however, there are an insufficient number of data points for hand exposure to use in the assessment (i.e., 10 data points vs. the 15 minimum required). The inhalation unit exposure values derived by Cheminova are the same as determined for the Surrogate Guide. For dermal exposure (excluding hands), the difference between the unit exposure determined by Cheminova (0.0105 mg/lb ai) and that determined for the Surrogate Guide (0.016 mg/lb ai) is not sufficient to cause a marked change in the overall risk for the mixing/loading of liquids scenario. Therefore, the Agency is using the unit exposure values from the PHED Surrogate Guide for mixing/loading liquids, based primarily on the larger number of replicates upon which the unit exposure value for hand exposure is based. Also, because the difference in the dermal unit exposure values is not sufficient to significantly change the dermal risk, it was decided not to mix PHED subsetted data for certain body parts with Surrogate Guide values for the remaining parts. The approach proposed by Cheminova warrants further consideration if more data for hand exposure become available for inclusion in the PHED.

b. Enclosed Cab Airblast Application

Comment 1: *There are no data in PHED with which to estimate exposures for the "no gloves" scenario while applying sprays in an enclosed cab airblast sprayer. EPA back-calculated the potential dermal exposure to the hands from the "gloves" enclosed cab scenario. Cheminova believes the 90% reduction factor used to back-calculate the "no gloves" potential exposure is unreasonable. Cheminova had previously recommended applying a 98% reduction factor to the "no gloves" PHED dermal unit exposure value for airblast application. EPA had disagreed, stating that this reduction factor was determined for flaggers in enclosed cabs. Cheminova does not find documentation in the PHED Guide for such a policy. Cheminova points out that the protection afforded by gloves is not significant when comparing the back-calculated "no gloves" unit exposure of 0.129 for enclosed cabs to the open cab "no gloves" unit exposure of 0.123.*

Likewise, comparing the unit exposures for groundboom, enclosed cab "gloves" (0.0009) and "no gloves" (0.000836), it is apparent that gloves do no contribute to hand protection. Therefore, Cheminova believes that the enclosed cab "no gloves" scenario should be estimated with the enclosed cab "gloves" dermal unit exposure value (0.019), i.e., without factoring in a 90% reduction factor for potential glove protection.

Response: EPA agrees and has calculated the airblast "no gloves" scenario using the enclosed cab "gloves" unit exposure. A notation (footnote) has been made in the assessment to describe the fact that the data do not show any significant added protection from wearing gloves in an enclosed cab.

c. Fogger application

Comment 1: *Cheminova agrees with EPA that the unit exposure for airblast application can be used as a reasonable surrogate for fogger application, but believes the assumption that a 90% reduction in the unit exposure for the "gloves" scenario is an unreasonable way to estimate the "no gloves" scenario (see b. above).*

***Response*:** EPA agrees for the reasons discussed in b. above, and has changed the unit exposure value used in the assessment accordingly.

d. Hose-end sprayer

Comment 1: *PHED does not contain PPE-mitigated unit exposure values for using hose-end sprayer. EPA did not use PPE reduction factors to calculate mitigated risks because risks were above the target MOE without such measures. Cheminova requests that EPA include PPE mitigated risks for all scenarios including this one, and provides the estimates when using the 50% reduction factor for a second layer of clothing and 90% for gloves.*

Response: The EPA risk assessment in the RED document presents PPE requirements for achieving the target MOE. The assessment is based on short-, intermediate and long-term toxicity endpoints. This assessment may result in mitigation requirements that are more or less stringent than those imposed under the Worker Protection Standard (WPS), which are based on acute toxicity of the end-use products. Final label requirements for PPE will be determined during the mitigation phase of the reregistration process, taking into account the requirements of the Worker Protection Standard and the indications for risk mitigation resulting from the EPA risk assessment. Addition of PPE requirements that are unnecessary to reach target MOEs or comply with the WPS, are not advised because they may result in heat stress or other health problems with no counter-balancing health benefit.

e. Flagging for Aerial Application

Comment 1: *For PPE-mitigated flagger risk, EPA assumed that flaggers would wear gloves and coveralls. Given the relatively small decrease in exposure associated with this PPE, Cheminova requests that EPA assume that flaggers will wear long-sleeved shirts, long pants and sturdy footwear. If correct application rates are used for ag (fruit and nuts) (i.e., 5 lb ai/acre), and for ULV mosquitoes (i.e., 0.23 lb ai/acre), the above recommended clothing will result in no flagging scenario associated with a risk below the target ARI of 1.*

Response: Adjustments in potential risks to flaggers have been made to reflect revised crop groupings and application rates.

9. Summary of Occupational Exposure and Risk Assessment by Cheminova

Comment 1: *Cheminova provides recalculated ARIs for all the handler scenarios in EPA's assessment, only using appropriate application rates and recommended changes listed above. In its re-assessment, all handlers (except for flaggers) are wearing long-sleeved shirts, long pants, chemical- or water-resistant gloves, socks and shoes. Only a few scenarios result in risks below an ARI of 1. Table of results are given.*

Response: Due to a change in the uncertainty factors associated with the inhalation toxicity endpoints, the ARI approach for risk assessment has been changed to a total MOE approach. As mentioned above, the EPA provides risk assessment calculations for PPE only where such mitigation is required to reach target MOEs. The PPE listed by the commentor are not always required to reach the target MOE based on toxicity of the active ingredient. In the Agency's calculations of handler risk, some scenarios require PPE, and only a few scenarios require engineering controls in order to reach target MOEs.

B. Occupational Postapplication Exposure and Risk Assessment

1. Use on Turf

Comment 1*: Cheminova is not supporting malathion application to turf, and therefore this scenario should be removed from the risk assessment.*

Response**:** Because registrants, other than Cheminova, have turf use on their labels, EPA must currently include an assessment of the exposure and risks to these products. Support for turf use must ultimately be agreed upon by all registrants of malathion to be removed from all registered product labels. This determination will be made during the risk mitigation phase of the reregistration process.

2. Dissipation Rate

Comment 1: *EPA has used transferrable residue data for malathion applied to turf in the postapplication risk assessment for all crops. Cheminova agrees with this approach. However, Cheminova requests that EPA make explicit in the assessment that the dissipation rate of 46% per day, which is based on the half-life of 13 hours, introduces a 2-fold decrease in the dissipation rate that would be expected in a full day (i.e., a 13-hour half-life corresponds to a 72% dissipation rate over 26 hours).*

Response**:** EPA has made clear in the revised assessment that a decreased value for daily dissipation rate than that found from turf studies has been used for agricultural postapplication exposure assessment. A rationale for this approach is also included.

Comment 2: *The overall (summary) risk assessment document contains more detail regarding the transferrable residue study results than the occupational assessment document from which the summary document was developed. This is inappropriate. For example, the summary document lists r^2 values and coefficients of variation for each regression analysis of the DFR data, while the occupational assessment lists only ranges.*

Response**:** The occupational assessment has been revised with more detail, including r^2 values and coefficients of variation for each regression analysis.

Comment 3*: There is no apparent correlation between the listed r and r^2 values for the North Carolina and Missouri sites. Also, the summary document lists an r^2 value of 1.000 for North Carolina data based on only two data points, while the document presents four data points in the data table. Cheminova requests that necessary corrections be made in both documents with regard to all of the above.*

Response**:** In the revised assessment, only the coefficients of determination (r^2 values) have been included. These values are a more standard indicator of variability for the regression analyses than the r values. For the North Carolina site, only the data collected at 0 and 4 hours following application were considered useable for purposes of the regression analysis. Other collection periods had no useable data (some because of rain events), or were at or below the LOQ and not believed to be good data points. Other data points indicated in the assessment for the North Carolina site (in brackets) are estimated values from the regression analysis on the two collected data points at 0 and 4 hours.

3. Transfer Coefficients

Comment 1: *Cheminova requests that EPA review and use recently submitted ARTF study results indicating appropriate dermal transfer coefficients for various crops. Cheminova believes these data provide substantially more accurate transfer coefficients than the standard values used by EPA. Cheminova gives examples of transfer coefficients developed by the ARTF for grape harvesting (1,500 cm^2/hr), apple thinning (2,771 cm^2/hr), apple harvesting (1,491 cm^2/hr), and apple propping (96 cm^2/hr). The apple thinning and grape harvesting studies have already been submitted to the EPA; apple harvesting and propping studies are planned to be submitted soon.*

***Response*:** EPA agrees that data and information generated by the ARTF should be used to the extent that they are currently available. In this regard, the HED Science Advisory Council for Exposure has developed a revised Policy Number 003.1 (revised August 7, 2000) that incorporates results from the ARTF Scoping Survey and data from submitted exposure studies and studies in the published literature. Crop groupings and transfer coefficients have been changed in the occupational postapplication assessment to reflect the guidance given in the new Exposure SAC Policy Number 003.1. The new transfer coefficients appearing in the assessment are based on an evaluation of currently available ARTF studies, and are generally lower than the ones used in the previous assessment. However, they differ from the ones cited by the commentor. Differences in approach to crop groupings and use of transfer coefficient data between the ARTF members and EPA are outside the scope of this comment/response effort for malathion. Further, the Exposure SAC Policy Number 003.1 will continue to be developed as new study data from the ARTF are received and evaluated by the Agency.

4. Estimated DFRs

Comment 1: *Table 12 of the occupational risk assessment reports DFR values with differing significant figures. Cheminova suggests that values in this table all be presented with two significant figures.*

***Response*:** EPA agrees and has reported new DFR estimates with two significant figures.

5. Crop Groups, Assumed Application Rates and REI Estimates

Comment 1: Cheminova believes some of the crop groups used by EPA in the postapplication assessment are too broad. EPA's grouping of "harvesting activities with a high degree of dermal contact" and "all activities on tree crops" should be split because the maximum application rates for these groups are different. EPA assumed a maximum application rate for this grouping to be 6 lb ai/acre, however, the maximum supported application rate for this grouping is 3.43 lb ai/acre (for tomatoes). The maximum supported rate for tree and nut crops is 6.25 lbs ai/acre, but this is for citrus. Supported rates for tree nuts (5 lb ai/acre), stone fruit (3.75 lb ai/acre) and pome fruit (1.25 lb ai/acre) are sufficiently different to warrant separate assessments. Cheminova, using the specific rates above, calculates non-harvesting and harvesting REIs of four and five days, respectively, for tomatoes. Cheminova estimates non-harvesting and harvesting REIs of six days for citrus, five days for stone fruit, three days for pome fruit and three to six days of various nut crops.

***Response*:** The crop groupings and application rates used for assessing occupational postapplication exposure have been revised. While it is not feasible to include every crop grouping and application rate, an effort has been made to cover major crop groups and application rates that will reasonably represent and bracket risks from malathion postapplication activities (see also, response to 4.a above).

Comment 2: *For crops with a medium degree of dermal contact, EPA assumed application rates from 0.5 to 4.0 lb ai/acre. Cheminova believes that a representative range of application rates is 0.61 to 3.43 and EPA should use this range.*

***Response*:** The crop groupings and application rates used for assessing occupational postapplication exposure have been revised. While it is not feasible to include every crop grouping and application rate, an effort has been made to cover major crop groups and application rates that will reasonably represent and bracket risks from malathion postapplication activities (see also, response to 4.a above).

Comment 3: *For crops with a low degree of dermal contact, EPA assumed application rates from 0.5 to 4.0 lb ai/acre. Cheminova believes that a representative range is 0.61 to 2.0 lb ai/acre, except for pineapples, which should be 5 lb ai/acre, and that EPA should use these values in its assessment.*

***Response*:** The crop groupings and application rates used for assessing occupational postapplication exposure have been revised. While it is not feasible to include every crop grouping and application rate, an effort has been made to cover major crop groups and application rates that will reasonably represent and bracket risks from malathion postapplication activities (see also, response to 4.a above).

Comment 4: *For mushrooms, EPA assumed an application rate of 2.0 lb ai/acre. The application rate for mushrooms, 0.039 lb ai/1,000 ft2, is equivalent to 1.7 lb ai/acre. EPA promised to verify the application rate and make revisions as appropriate. A change to 1.7 lb ai/acre results in the same REI of 2 days.*

***Response*:** EPA agrees and has revised the assessment to show a 1.7 lb ai/acre rate for mushrooms.

6. Comparison of EPA and Cheminova Estimated REIs

Comment 1: Cheminova presents a summary table of REIs calculated for "high end" and "low end" crops by EPA with REIs that it calculated for a range of typical application rates for each crop group using ARTF transfer coefficients available for apples and grapes, and EPA standard transfer coefficient values for all other REIs.

***Response*:** See response to 3. above.

C. Residential Application Exposure and Risk Assessment

1. Turf Application

Comment 1: *Cheminova is not supporting application of malathion to turf, either by homeowners or commercial applicators, and all residential turf scenarios should, therefore, be removed from the residential assessment.*

***Response*:** Because turf uses (e.g., Ortho® Malathion 50 Insect Spray, EPA Reg. No. 239-739, sprayed on lawns to control clover mites) are currently registered, their potential exposures and risks are included in the current assessment. If official removal of these uses for malathion is to occur, it will be done during the risk mitigation phase of the reregistration process.

2. Application Rates for Homeowner Uses

Comment 1: EPA has used maximum application rates for fruit trees and ornamentals (0.034 lb ai/gal) and vegetables (0.023 lb ai/gal). While the maximum rate from Cheminova's labels for these uses are 0.030 lb ai/gal and 0.020 lb ai/gal, respectively. Cheminova appreciates EPA's agreement to review and verify maximum application rates for these uses.

Response: EPA has reviewed the label from which it derived the rates used in its homeowner assessment of malathion on fruit trees and ornamentals (i.e., Ortho® Malathion 50 Plus, EPA Reg. No. 239-739). The Agency found that the rates used are accurate and do not need to be changed in the revised assessment.

3. Shaker Can Exposure

Comment 1: *No data are available in PHED for estimating residential applicator exposure to dust formulations in a shaker can. EPA used the assumption that the applicator is exposed to 10% of the active ingredient (taken from the EPA Draft Residential Exposure Guidelines for estimating pet products). Cheminova believes it is unreasonable to use a pet application scenario for estimating home garden use, and recommends using the*

unit exposure for mixing/loading and applying wettable powder with a low-pressure handwand. The dermal unit exposure for this scenario (i.e., 250 mg/lb ai, taken from the EPA Draft Standard Operating Procedures for Residential Exposure Assessments, December 18, 1997) is similar to one used in the Chlorpyrifos assessment (220 mg/lb ai), taken from a study in the open literature.

Response: The Agency agrees and has assessed the dust shaker can exposure scenario using the Draft Residential Exposure SOP unit exposure values (dermal and inhalation) for mixing/loading/applying wettable powders using a low-pressure handwand.

4. Summary of Residential Exposure and Risk Assessment by Cheminova

Comment 1: *Cheminova has presented residential exposures and risks calculated with the above comments incorporated. Results are similar to those of EPA, except that the dust shaker can risk estimated by Cheminova exceeds the target ARI, while EPA's does not.*

***Response*:** In EPA's revised risk assessment, the dust shaker can risk is above the target MOE established for this scenario and therefore, does not trigger the Agency's concern for this scenario.

D. Residential Postapplication Exposure and Risk Assessment

1. Errors

Comment 1: *Under section 3.2.3, inhalation rates are listed in terms of m^3. Rates should be listed as m^3/hour.*

***Response*:** Inhalation rates have been revised to m^3/hour.

Comment 2: *In Table 17, the DFR for turfgrass ingestion for ULV application is incorrectly listed as 0.008 ug/cm^2. The correct value is 0.00080 ug/cm^2.*

***Response*:** Table 16 (not 17) has been changed to list the correct DFR value for turfgrass ingestion following ULV application (i.e., changed to 0.0008 ug/cm^2). Calculation of the MOE has been made based on the revised value.

2. Turf-Related Exposure Scenarios

Comment 1: *Cheminova is not supporting turf uses and believes postapplication exposure scenarios involving turf should be limited to residues from mosquito control spraying.*

***Response*:** Because turf uses (e.g., Ortho® Malathion 50 Insect Spray, EPA Reg. No. 239-739, sprayed on lawns to control clover mites) are currently registered, their potential exposures and risks are included in the current assessment. If official removal of these uses for malathion is to occur, it will be done during the risk mitigation phase of the reregistration process.

3. Application Rate Assumptions

Comment 1: *In estimating DFRs for malathion on garden plants and pick-your-own strawberries, EPA assumed that 5 gallons of spray (0.023 lb ai/gal) would be applied to 1000 ft^2 (equivalent to 5.0 lbs ai/acre). This is considerably higher than the maximum label rate of 2.0 lb ai/acre. The EPA Draft SOPs support application of 5 gallons of spray to 10,000 ft^2. Thus, EPA's assumption of 5 gallons to spray 1,000 ft^2 results in an overestimate of initial DFR. EPA should re-calculate the risk using the application rate of 2.0 lb ai/acre.*

***Response*:** EPA agrees and has recalculated the residential postapplication risks from contact with garden plants and pick-your-own strawberries using the conversion factor of 5 gallons of spray per 10,000 ft^2 as implied in the

EPA Draft Residential Exposure SOPs.

Comment 2: *In estimating DFRs for malathion on ornamentals, EPA assumed that 5 gallons of spray (0.034 lb ai/gal) would be applied to 2000 ft^2 (equivalent to 3.7 lbs ai/acre). This is considerably higher than the maximum label rate of 2.6 lb ai/acre. The EPA Draft SOPs support application of 5 gallons of spray to 10,000 ft^2. Thus, EPA's assumption of 5 gallons to spray 2,000 ft^2 results in an overestimate of initial DFR. EPA should re-calculate the risk using the application rate of 2.6 lb ai/acre.*

***Response*:** EPA agrees and has recalculated the residential postapplication risks from contact with ornamentals using the conversion factor of 5 gallons of spray per 10,000 ft^2 as implied in the EPA Draft Residential Exposure SOPs.

4. Exposure Assumptions

Comment 1: *EPA assumed toddlers would spend 2 hours per day in the garden, while the Draft Residential SOPs list the correct value as 0.33 hours per day. Cheminova requests that EPA recalculate the risk for this scenario using the correct assumption.*

***Response*:** EPA agrees and has recalculated the postapplication risk to toddlers in vegetable gardens using the exposure duration of 0.33 hours as given in the EPA Draft Residential SOPs.

5. Dissipation Rate

Comment 1: *In calculating the dissipation rate of malathion from turf, EPA states that the empirically-derived 13-hour half-life corresponds to a 46 percent dissipation per day. However, a 13-hour half-life actually corresponds to a 72 percent dissipation rate. The doubling of the half-life for turf may be appropriate when using the turf data to estimate DFR for other crops, but should not be done when estimating postapplication exposure to treated turf. The dissipation rate of 72 percent per day on turf should be included in the text of the assessment, even though Cheminova is not supporting turf use and requests that all assessments of this use be removed from the document.*

***Response*:** The text describing the dissipation rate of malathion on turf has been deleted from this residential postapplication section. The only datum relevant to the postapplication residential assessment is the amount of residue assumed to be initially available to dislodge or transfer. From the regression analysis of actual turf residue data, a 1.3% value was determined for the amount of the application rate initially available to transfer to skin. This value was used for residential turf exposure scenarios except for toddler hand-to-mouth incidental ingestion. For this scenario, a value of 5% of the application rate was used to account for the additional residue that may be removed by "sticky" hands. For other crop use sites (e.g., vegetable/small fruit gardens), the standard HED value for initial available residue of 20% was used.

6. Summary of Residential Postapplication Exposure and Risk Assessment by Cheminova

Comment 1: *Cheminova calculated residential postapplication risks using EPA scenarios, but incorporating comments above. Cheminova's calculations and conclusions are similar to EPA's except where different assumptions regarding application rates for gardens, strawberries, fruit trees and ornamentals caused different MOEs for postapplication exposure.*

***Response*:** EPA has recalculated certain residential postapplication risks per response to comments as described above.

E. Boll Weevil Eradication Program

Comment 1: *Cheminova believes that the dermal unit exposure for open pour mixing/loading of liquids from the PHED Surrogate Guide is not based on a representative data set. Cheminova reevaluated the data in PHED and generated a refined dermal unit exposure estimate of 10.7 mg/lb ai for open pour mixing/loading of liquids*

and requests that EPA use this value in its calculation of mixer/loader exposures. When Cheminova uses this unit exposure value, it estimates and ARI of 0.95 for mixer/loaders wearing standard work clothes, plus gloves. Therefore, additional PPE requirements for mixers/loaders are not implicated.

***Response*:** EPA assumes that Cheminova had used a similar approach to subsetting PHED data as was suggested above, under comment, F. Unit Exposures, a. Open Pour Mixing/Loading of Liquids, Comment 1. If this is true, EPA agrees with the approach suggested, however, there are an insufficient number of data points for hand exposure to use in the assessment (i.e., 10 data points vs. the 15 minimum required). The inhalation unit exposure values derived by Cheminova are the same as determined for the Surrogate Guide. For dermal exposure (excluding hands), the difference between the unit exposure determined by Cheminova (0.0105 mg/lb ai) and that determined for the Surrogate Guide (0.016 mg/lb ai) is not sufficient to cause a marked change in the overall risk for the mixing/loading of liquids scenario. Therefore, the Agency is using the unit exposure values from the PHED Surrogate Guide for mixing/loading liquids, based primarily on the larger number of replicates upon which the unit exposure value for hand exposure is based. Also, because the difference in the dermal unit exposure values is not sufficient to significantly change the dermal risk, it was decided not to mix PHED subsetted data for certain body parts with Surrogate Guide values for the remaining parts. The approach proposed by Cheminova warrants further consideration if more data for hand exposure become available for inclusion in the PHED.